NOT FOR PUBLICATION (Doc. No. 205)

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| SCIELE PHARMA INC., (N/K/A SHIONOGI PHARMA INC.), ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC., FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC. ANDRX EU LTD., and ANDRX LABS, L.L.C., | : | |
| Plaintiffs, | : | Civil No. 09-0037 (RBK/JS) |
| v. | : | |
| LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., and MYLAN INC., and MYLAN PHARMACEUTICALS, INC. | : | |
| Defendants. | : | |

**KUGLER**, United States District Judge:

This matter comes before the Court on the motion of Plaintiff Sciele Pharma Inc., now known as Shionogi Pharma Inc., for a preliminary injunction to prohibit Lupin Ltd. ("Defendant") from further importation and sales of its generic version of Plaintiff's Fortamet® drug, and for a recall of Defendant's product already in the market.[1] For the reasons expressed below, the Court grants Plaintiff's motion for preliminary injunction, on the condition that

[1] The Court notes that Plaintiff Shionogi's motion does not seek relief as regards the Mylan Inc. Defendants. Moreover, although this motion is brought only by Shionogi, the Andrx Plaintiffs do not oppose it. Pl. Br. in Support of Preliminary Injunction (hereinafter "Pl. Br. Prelim. Inj."), 1 n.1.

Plaintiff post the necessary security pursuant to Federal Rule of Civil Procedure 65(c), but denies Plaintiff's motion for recall of Defendant's already-distributed product.

## I. BACKGROUND[2]

Along with the Andrx Plaintiffs, Plaintiff Shionogi is a licensee and patent holder of U.S. Patent Nos. 6,099,859 ("'859") and 6,866,866 ("'866"), which are embodied in Fortamet®, an extended-release metformin hydrochloride tablet developed and distributed by Shionogi. Sciele Pharma, Inc. v. Lupin Ltd., 09-cv-37, 2011 U.S. Dist. LEXIS 105572 (D. Del. Sept. 15, 2011) (hereinafter "Markman Op."), *4. The metformin hydrochloride tablet is used, along with diet and exercise, to lower blood glucose in adults with Type 2 diabetes mellitus. Id. at *9. Plaintiff's drug is designed to control the release and create an extended-release dosage form of metformin. Id. at *10. The '866 Patent claims that Fortamet®'s mean time to maximum plasma concentration—$T_{max}$, the time when the level of drug in the patient is highest—is from 5.5 to 7.0 hours ('866 claim 3), or 5.5 to 7.5 hours ('866 claims 1, 25). Pl. Br. Prelim. Inj., 13.

On or about December 3, 2008, Lupin sent a notice letter to Plaintiff Andrx, in which Lupin indicated that it had filed an Abbreviated New Drug Application ("ANDA") that included certifications for '859 and '866, and that it was seeking approval of its ANDA prior to the expiration of those patents. Markman Op., *4-5. Plaintiffs filed suit for patent infringement against Defendant, pursuant to the Hatch-Waxman statute, 21 U.S.C. § 355(j). Id. at *5.

On September 7, 2011, this Court held a claim construction hearing, pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). A claim construction Opinion and Order were filed on September 15, 2011. Plaintiff alleges in the brief accompanying its

[2] This Court's Opinion following the claim construction hearing in this matter, Sciele Pharma, Inc. v. Lupin Ltd., 09-cv-37, 2011 U.S. Dist. LEXIS 105572 (D. Del. Sept. 15, 2011) (hereinafter "Markman Op."), details the facts underlying this pharmaceutical patent dispute. Accordingly, this Opinion sets out only those facts directly relevant to the instant motion for preliminary injunction and recall.

instant motion that, on September 30, 2011, Defendant notified Plaintiff that it was terminating the two parties' settlement negotiations, and consequently terminating two preliminary agreements that were executed contingent upon reaching the final terms of an agreement whereby Lupin would promote Fortamet® in the United States. Pl. Br. Prelim. Inj., 9. Plaintiff claims that, on September 30, 2011, Plaintiff "began to hear rumors" that Lupin had launched or would soon launch its generic version of Plaintiff's drug. Id.[3]

Indeed, Lupin launched its product on September 30, 2011. Noyes Decl., Ex. 8. Plaintiff filed its motion for Preliminary Injunction on October 12, 2011. On October 17, 2011, this Court entered an order enforcing a standstill agreement reached by the two parties, wherein Defendant agreed not to further release or in any other way make plans to distribute its product, and Plaintiff agreed not to release or in any other way make plans to distribute a generic version of Fortamet® until November 15, 2011, until one of the parties' failed to file its brief for the preliminary injunction motion, or until this Court's decision regarding the preliminary injunction was entered. 09-cv-37, Doc. No. 217. That standstill agreement was subsequently extended until December 3, 2011. 09-cv-37, Doc. No. 273. On December 2, 2011, this Court heard oral argument on Plaintiff's motion for preliminary injunction. At that hearing, the parties agreed to further extend the standstill agreement for one more week.

## II. STANDARD

An injunction is an equitable remedy, which "should issue only where the intervention of a court of equity 'is essential in order effectually to protect property rights against injuries

[3] The parties appear to dispute whether or not Lupin's launch was "stealth." Shionogi claims that it was unaware of the launch until it asked Lupin directly, on October 2, 2011, whether or not it planned to launch its product, and heard from Lupin's counsel on October 3, 2011, that it had launched its product on September 30, 2011. Pl. Br. Prelim. Inj., 9. Defendant argues that a Lupin executive had informed Shionogi of the likelihood of such a launch, and the launch itself had been publicly announced by Lupin's Chief Financial Officer in the Wall Street Journal and elsewhere two days before the launch took place. Def. Br. Opp., 30-31. This dispute is not of substantial import to the Court.

otherwise irremediable.'" Weinberger v. Romero-Barcelo, 456 U.S. 305, 311-12 (1982) (quoting Cavanaugh v. Looney, 248 U.S. 456 (1919)). A plaintiff seeking a preliminary injunction must show (1) a likelihood of success on the merits; (2) irreparable harm to the movant if no injunction is granted; (3) that the balance of hardships favors the granting of injunctive relief to the plaintiff; and (4) that the public interest would not be disserved by injunctive relief. Ranbaxy Pharms., Inc. v. Apotex, Inc., 350 F.3d 1235, 1239 (Fed. Cir. 2003). The Supreme Court articulated in eBay Inc. v. MercExchange, that "[t]he decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court." 547 U.S. 388, 394.

The eBay Court deemed it necessary to elucidate that the four-factor injunction test applies equally in the context of patent litigation as in substantive areas of the law, because the Court found that the Federal Circuit had "departed . . . from the four-factor test" by "articulat[ing] a 'general rule,' unique to patent disputes, 'that a permanent injunction will issue once infringement and validity have been adjudged.'" Id. at 393-94 (citing MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005)). Federal Circuit case law had entrenched the notion that "[a] court should not be reluctant to use its equity powers once a party has so clearly established his patent rights." Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983). Moreover, the Federal Circuit had determined that "immediate irreparable harm is presumed" where "validity and continuing infringement have been clearly established." Id. (finding that "to hold otherwise would be contrary to the public policy underlying the patent laws"). Addressing this interpretation of the conditions under which injunctive relief may be granted, the eBay Court emphasized that the "familiar principles" forming the standard for

injunctive relief "apply with equal force to disputes arising under the Patent Act." eBay, 547 U.S. at 391.

Very recently, in Robert Bosch LLC v. Pylon Manufacturing Corp., the Federal Circuit took the "opportunity to . . . confirm that eBay jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief." 2011 U.S. App. LEXIS 20700 at *13 (Fed. Cir. Oct. 13, 2011). Nevertheless, the Federal Circuit stated, "[a]lthough eBay abolishes our general rule that an injunction normally will issue when a patent is found to have been valid and infringed, it does not swing the pendulum in the opposite direction." Id. at *14. Accordingly, Bosch indicates that, although the Circuit will no longer apply the mechanical presumption of a finding of irreparable harm where a likelihood of success on the merits has been found, it will continue to apply its established "legal standards that inform the four-factor [injunction] inquiry and, in particular, the question of irreparable harm." Id. at *17.

## III. DISCUSSION

### A. Likelihood of Success on the Merits

In order for Shionogi to prevail on this prong, it must demonstrate a likelihood that it would succeed on its claim that Lupin has infringed either the '859 or '866 patents (or both), and that Shionogi's "infringement claim will likely withstand [Defendant's] challenges to the validity and enforceability" of the patents. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). Shionogi must show that it is likely to prove at trial that Lupin "infringes at least one valid and enforceable patent claim." Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1201 (Fed. Cir. 2007). Moreover, if Lupin "raises a substantial question concerning either infringement or validity, . . . the preliminary injunction should not issue."

Amazon.com, 239 F.3d at 1350-51. This Court finds that Plaintiff has shown a likelihood that it will succeed on the merits its noninfringement claim, and that its patent will be found valid.

1. Noninfringement

The focus of both Plaintiff's and Defendant's arguments concerning Lupin's potential infringement of Shionogi's patent rights is one limitation found in the '866 patent—namely, the mean time to maximum plasma concentration ("$T_{max}$"). Pl. Br. Prelim. Inj., 14; Def. Br. in Opposition to Plaintiff's Motion (hereinafter, "Def. Br. Opp."), 10. Plaintiff submits that the $T_{max}$ range of the '866 patent is the only patent limitation that, according to Defendant, Defendant's generic product does not infringe. Pl. Br. Prelim. Inj., 13-14 (citing Lupin's 2008 "Paragraph IV certification," required by 21 U.S.C. § 355(j)(2)(B)(iv)(II); and Lupin's 2010 Non-Infringement Contentions, Noyes Decl., Ex. 9)). Defendant counters that this is the only patent limitation for which Plaintiff chooses to raise an issue of infringement; therefore, this is the only patent claim that Defendant addresses in its briefing on this issue. Def. Br. Opp., 10. Accordingly, this is the only patent claim that this Court will address in determining Plaintiff's likelihood to succeed on the merits of its infringement claim.

a) Defendant's $T_{max}$ Study

Specifically, Plaintiff's '866 patent indicates that Plaintiff's drug provides a mean time to maximum plasma concentration of 5.5 to 7.5 hours or 5.5 to 7.0 hours. See '866 Patent, claim 1 ("the dosage form provides a mean time to maximum plasma concentration ($T_{max}$) of the metformin from 5.5 to 7.5 hours after administration following dinner"); '866 Patent, claim 3 (claiming "[t]he controlled release oral dosage form of claim **1**, which provides a mean time to maximum plasma concentration ($T_{max}$) of metformin 5.5 to 7.0 hours after the administration of the dose"). Plaintiff argues that the FDA-approved label for Lupin's drug indicates a $T_{max}$ of 6

hours when administered after dinner. Pl. Br. Prelim. Inj. 14. This puts the $T_{max}$ of Defendant's drug squarely within the range claimed by Plaintiff's '866 patent, Plaintiff argues, and therefore shows that Lupin's product infringes at least one claim of Plaintiff's patent. Id.

Defendant, on the other hand, presents a study demonstrating that, for Lupin's product, "mean time to maximum plasma concentration was 12.8 hours" when a single dose was administered after dinner, "with no subject exhibiting a $T_{max}$ of less than 12 hours." Def. Br. Opp. 10. As Lupin's expert, Alexander Shepherd, M.D., Ph.D., FAHA, explains, Lupin presents data from (1) a study of its drug performed when the subjects were not fed, (2) a study performed after the subjects were fed breakfast, and (3) a study performed after the subjects were fed dinner. Shepherd Decl. at ¶ 6. Ten subjects participated in the after-dinner study. Id. at ¶ 7. The after-dinner study revealed a mean observed $T_{max}$ of 12.8 hours, with a standard deviation of +/- 1.7 hours. Id. at ¶ 8. Thus the study put the $T_{max}$ of Lupin's project more than 2 standard deviations away from falling into the $T_{max}$ range claimed in the '866 patent. Dr. Shepherd explains that this means that "one is 95% confident that if the Lupin metformin product was administered to another ten similar subjects following dinner, those subjects would all exhibit $T_{max}$ values between 9.4 (12.8 – 3.4) and 16.2 (12.8 + 3.4) hours." Id.

However, Plaintiff argues that Lupin's study is "fundamentally flawed and unreliable" because it does not identify the drug being tested by lot number or date of manufacture. Pl. Br. Prelim. Inj. 16. Plaintiff's expert, Lawrence Fleckenstein, Pharm.D., suggests that "a well-documented study would contain this information." Fleckenstein Decl. at ¶ 64-65. Moreover, Plaintiff argues that the results of Lupin's study "are skewed because it only tested 10 subjects." Pl. Br. Prelim. Inj. 16. Although Dr. Fleckenstein avers that a 10-subject test may be statistically reliable, he explains that it is subject to being disproportionately affected by outliers,

"especially . . . when $T_{max}$ values get particularly high, such as 12, 16, or 20 hours after administration." Fleckenstein Decl. at ¶ 56. Dr. Fleckenstein offers the opinion that "the 10-subject sample in [Lupin's study] caused the significant variability and led to skewed [sic] $T_{max}$ figure." Id. at ¶ 57. However, as Lupin's expert explains, not even "a single subject data point in Lupin's study falls within the 5.5 to 7.5 hour range," so it is notable that there appear to be no outliers to speak of in the Lupin study. Shepherd Decl. at ¶ 8.

Plaintiff's expert also reports an "upward bias" of the $T_{max}$ in Defendant's study, due to "infrequent sampling near the tail end of the relevant period following administration."[4] Fleckenstein Decl. at ¶ 58-59. Defendant responds that "this criticism is truly irrelevant" because the only potential effect of more frequent sampling would be to drive the $T_{max}$ value "from 12.8 to slightly lower," which "would not change the conclusion of non-infringement because no [subject of the study] had a $T_{max}$ below 12 hours, and thus the mean $T_{max}$ could not be less than 12 hours." Def. Br. Opp. 12 (emphasis omitted).

Plaintiff also argues that Lupin's study is "fundamentally flawed" for lack of use of a reference control drug. Pl. Br. Prelim. Inj. 17. Moreover, Plaintiff complains that Lupin's study provides "no dissolution data" that would "help[] the reader understand the release characteristics and release timing of the dosage form," and therefore makes it "impossible to know when the tested drug was released in a patient's system, and in what amounts." Id. at 18. Finally, Plaintiff, through its expert, points out that Lupin's study does not describe its purpose, and that, as a consequence, its results are "unreliable and unacceptable." Id. Defendant, through its own expert, dismisses these concerns by arguing that the criticisms raised by Plaintiff would

[4] Plaintiff offers the following example: "assume for a particular patient in [Lupin's study] that $T_{max}$ truly occurred at 16.5 hours after administration of the drug. However, in this study the investigator only sampled the blood of the patient at 16 hours, and then again at 20 hours. Therefore, the investigator will have missed the true $T_{max}$ point by 3.5 hours," and "will report $T_{max}$ as 20 hours, when in fact it is much earlier. As such , the mean value will skew upwards." Fleckenstein Decl. at ¶ 59.

not have changed the result of the study, and also argues that certain of Shionogi's studies supporting its '866 patent exhibit the same purported flaws. Def. Br. Opp. 12.

Thus, Defendant's study offers evidence that Defendant's product may not infringe Plaintiff's '866 patent, while Plaintiff's critique raises doubts as to the validity of Defendant's study. This battle of the experts prevents the Court from concluding that Defendant "raises a substantial question" as to its nonfringement of Plaintiff's patent. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001) (emphasis added). To further examine Plaintiff's likelihood of success on the merits, the Court turns to the issue raised by Shionogi concerning the label on Defendant's generic product.

b) Defendant's Label

Plaintiff argues that "Lupin's sole non-infringement argument—that its generic copy of FORTAMET falls outside the range for $T_{max}$—is directly contrary to the FDA-approved label for its product. Pl. Br. Prelim. Inj. 14. Plaintiff points out that, in the "Pharmacokinetics and Drug Metabolism" section of the patent, "Lupin's approved label states that metformin extended-release tablets have a mean $T_{max}$ of 6 hours when administered after dinner." Id. (see also Fleckenstein Decl. at ¶ 53). Lupin does not dispute that its label expresses that $T_{max}$. However, Defendant argues that its product "is bioequivalent to Fortamet®, but not identical to Fortamet®" for the "parameters of interest according to the FDA." Def. Br. Opp. 5. Lupin further contends that its label specifies a $T_{max}$ of 6 hours because of "FDA regulations requiring that the generic drug's labeling be the same as that of the brand drug . . . ." Id.

As Plaintiff explains, Lupin's argument is unavailing because strong Federal Circuit precedent has rejected it already. For example, in Abbott Labs. v. Torpharm, Inc., the defendant "state[d] that its package insert must by law duplicate" the plaintiff's. 300 F.3d 1367, 1374 n.2.

The Circuit noted that "a manufacturer may petition . . . for labeling different from that of the reference listed drug . . . ." Id. Where the defendant had not indicated whether such a petition had been filed (as is the case here with Lupin), the Circuit did not accept the argument that the defendant's legal obligation to duplicate the patentee's insert erased the defendant's avowal of the information contained therein. Thus the Federal Circuit underscored that "an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." Abbott Labs. v. Torpharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002). In this case, Defendant has not filed a petition to vary its label specifications from those of Fortamet®; thus, we continue to operate under the rule of Abbott Laboratories, and find that the ANDA specifications of Defendant's product control this Court's infringement inquiry.

Defendant further argues that the Supreme Court's ruling in Pliva, Inc. v. Mensing establishes that "brand-name and generic drug manufacturers have different federal drug labeling duties." 131 S.Ct. 2567, 2574 (June 23, 2011) (cited in Def. Br. Opp. 15). However, Pliva's clarification of warning-label requirements does not establish the proposition that a generic drug's label has no bearing on its infringement of the brand-name drug's patent. In fact, the Pliva Court neither abrogated nor even mentioned Abbott Laboratories v. Torpharm, wherein, as indicated above, the Federal Circuit established as law that a generic drug's labeling controls the question of infringement. 300 F.3d 1367, 1373 (Fed. Cir. 2002). Moreover, since the Supreme Court's decision in Pliva, the Federal Circuit has only underscored its ruling in Abbott Laboratories, and seems to make no reference to Pliva when considering drug labeling in the infringement context. See In re Brimonidine Patent Litig.; Allergan, Inc. v. Exela Pharmsci Inc.,

643 F.3d 1366, 1378 (Fed. Cir. 2011) (citing Abbott Labs. for the proposition that a generic drug's ANDA specifications control the infringement inquiry).

Accordingly, the Court finds that since a generic drug's label is found to control the analysis of potential infringement in a case like this one, and since Defendant's label reflects a $T_{max}$ that falls within the range claimed in Plaintiff's patent, Plaintiff has shown a likelihood that Defendant's drug infringes a claim of the '866 patent.

2. Invalidity

Shionogi is likely to succeed in its claim that its patent is valid because of the strong presumption favoring the validity of existing patents. See Canon Computer Sys. v. Nu-Kote Int'l, 134 F.3d 1085, 1088 (Fed. Cir. 1998) ("[A] patent is presumed valid, and this presumption exists at every stage of the litigation."). Furthermore, a challenger must prove invalidity by clear and convincing evidence—a high threshold that Lupin cannot meet at this stage. See Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (U.S. 2011) ("We consider whether § 282 [of the Patent Act of 1952] requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.").

Defendant's argument is that the '866 patent was erroneously granted. Def. Br. Opp. 22. Specifically, Defendant reviews the prosecution history of the '866 patent, arguing that claim 1's $T_{max}$ of 5.5 to 7.5 hours had been rejected as obvious. Id. Therefore, Lupin contends, the patent examiner intended to approve only "claims with a $T_{max}$ ceiling of '7 hours' in the face of prior art." Id. The fact that Plaintiff's claim 1 reads "7.5 hours" is therefore a mistake, according to Lupin, and undercuts "[t]he rationale underlying the presumption of validity . . . that the PTO, in its expertise, has approved the patent claims . . . ." Id. Defendant's expert, himself a former

Patent and Trademark Office ("PTO") examiner, concludes that "[c]laims 1 through 25 listed in the '866 patent were not the claims which the USPTO ultimately allowed." Steiner Decl. at 39.

Plaintiff emphasizes the fact that claim 1 was allowed by the PTO on December 19, 2003. See Sutherland Decl. Ex 2. Nevertheless, Plaintiff's version of the prosecution history does corroborate that there was some measure of confusion at the PTO regarding the '866 patent. Specifically, it is unclear how claim 1 came to be included in the final version of the patent, since the patentees appear to have sent a communication to the PTO on January 8, 2004, requesting certain changes to their application—including the cancellation of claim 1. Sutherland Decl. Ex. 4. This is particularly puzzling given that the PTO issued a Supplemental Notice of Allowability on November 15, 2004, which purportedly deleted claim 1. Id. at Ex. 5; see also Pl. Reply Br 11 n.11. As Lupin's expert articulates, "[i]t cannot be said with certainty how the error occurred." Steiner Decl. at 39.

Despite this puzzling history, however, it cannot be overlooked that claim 1, as it appears in the '866 patent, was indeed approved by the PTO on December 19, 2003. Sutherland Decl. Ex. 2. Thus the Court finds that, whatever confusion followed the PTO's notice of allowability approving (among other claims) claim 1, no substantial question as to the validity of the claims contained within the '866 patent has been raised. This is especially true given that "[t]he presumption [of a patent's validity] is never annihilated, destroyed, or even weakened, regardless of what facts are of record." ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1574-1575 (Fed. Cir. 1984). Given this presumption, and faced with the very steep requirement that the Defendant show clear and convincing evidence of the invalidity of Plaintiff's patent, the factual dispute concerning the prosecution of the '866 patent is not sufficient to persuade the Court to resolve the question of validity in Defendant's favor at this preliminary stage.

**B. Irreparable Harm**

Plaintiff argues that Defendant's launch will cause it to suffer irreparable harm in the form of lost revenue, lost market share, lost jobs, a loss of its formulary status, further economic harm from the potential release of Andrx's own authorized generic product, and loss of goodwill. Pl. Br. Prelim. Inj. 23-29. Defendant Lupin responds that these alleged harms are either compensable by monetary damages, particularly given that Defendant "is more than able to pay any damages that might be awarded," or else they are too speculative to constitute irreparable injury. Def. Br. Opp. 23. Because Shionogi has made sufficient showing that it will suffer loss of market share, price erosion, and loss of goodwill, the Court finds that, according to the Federal Circuit's standards, Plaintiff has shown that it will suffer irreparable harm if the Court does not grant a preliminary injunction.

1. Plaintiff's Anticipated Loss of Goodwill

Shionogi projects that its goodwill will suffer as a result of the entry of Defendant's generic drug. Pl. Br. Prelim. Inj. 27-28. Plaintiff indicates that it "will no longer have control over the quality and service aspects of consumer satisfaction" associated with its drug. Id. at 27. If prescriptions for Fortamet® are filled with Lupin's generic, as Plaintiff can expect they will be (see discussion of state substitution laws, III.B.2 infra), then those patients receiving "Lupin's potentially inferior generic product may be permanently dissatisfied with what they believe to be Shionogi's product." Id. Moreover, Shionogi suggests, "[c]ustomers may blame Shionogi for price fluctuations" that follow Lupin's launch—"[s]pecifically, consumers may blame Shionogi for the removal of a less expensive generic from the market" if the Court does not issue a preliminary injunction now, but enjoins Lupin's distribution of its generic later. Id.

The Federal Circuit has found that such loss of goodwill contributes to a finding of irreparable harm. See, e.g., Bio-Technology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1566 (Fed. Cir. 1996). This Court finds that, on its own, the loss of goodwill claimed by Shionogi is not sufficient to constitute irreparable harm, particularly because, as Lupin argues, Shionogi's projected loss of goodwill remains "speculative," Def. Brief. Opp. 28, and is based primarily on flippant language in one email sent internally between Defendant's employees. See Dec. 2, 2011Hearing. Nevertheless, the potential for such a loss of goodwill must factor into the Court's analysis of the irreparability of the harm to Shionogi.

2. Plaintiff's Projected Economic Losses

Concerning its projected loss of revenue, Shionogi states that it expects "to lose significant share to Lupin" if no injunction is granted. Vellturo Decl. at ¶43. Specifically, Shionogi projects that, from October 2011 to March 2012, Plaintiff's net sales will decrease to 41 percent of what they would have been in the absence of Lupin's generic entry. Id. Shionogi predicts that, from April 2012 to March 2013, that figure will fall to 13 percent. Id. Accordingly, if Lupin's product remains in distribution channels while Plaintiff awaits trial, Plaintiff avers, it is "quite possible" that, in the absence of injunctive relief, "Fortamet® could lose up to 90 percent of its sales while Lupin's generic metformin extended release products are in the marketplace, a period that . . . could well last nearly a year . . . ." Id. at ¶ 44. Plaintiff attributes much of this projected loss to the "high rate of generic penetration," which is due in large part to substitution laws that exist in 38 U.S. states of United States. Id. at ¶¶ 29, 33. These laws either mandate or permit the dispensing of generic drugs ("AB-rated" generics) that according to the FDA, are bioequivalent to the branded drug. Id. at ¶ 33.

In Bosch, the Federal Circuit indicated that, although the burden of showing lost market share rests on the party seeking injunctive relief, nevertheless that showing "need not be made with direct evidence." Bosch, 2011 U.S. App. LEXIS 20700 at * 29. The Bosch Court found circumstantial evidence of such loss to be sufficient. Id. In this case, Shionogi presents comparable examples to illustrate the harm to branded products when an AB-rated generic enters the market. Vellturo Decl. at ¶ 32. Specifically, Plaintiff offers the examples of Plavix® and Protonix®, detailing the harm to sales in the brand-name drug when the generic product was launched. Along with Plaintiff's projected losses, these examples offer a "prima facie showing of lost market share," as required by Bosch. Bosch, 2011 U.S. App. LEXIS 20700 at * 29. Moreover, Plaintiff represented to this Court that its sales have dropped by 50 percent in the time since Lupin's launch, despite the fact that Lupin's product was injected into the stream of commerce only for little over two weeks before the parties reached their standstill agreement. Dec. 2, 2011 Hearing. Lupin does not offer evidence to refute Plaintiff's prima facie showing that Plaintiff will suffer a loss in market share if Lupin's launch is permitted to continue. Thus because, as in Bosch, Defendant "proffer[s] no evidence to rebut that showing," and Plaintiff's projected loss in market factors into a finding of irreparable harm. Bosch, 2011 U.S. App. LEXIS 20700 at * 29.

Lupin argues that a showing of lost market share alone is not proof of irreparable harm, and this Court agrees. Def. Br. Opp. 25. But in addition to demonstrating a projected loss in its sales, Plaintiff argues that Lupin's entry into the market will create price erosion. Shionogi explains that "typically the branded drug manufacturer is forced to offer discounts, rebates, or other incentives that lower the price of the drug." Id. Furthermore, according to Plaintiff, Defendant's launch puts it at risk of losing its Tier II formulary status with certain commercial

third-party payors ("TPPs"), such as CIGNA, Humana, Express Scripts, and two Medicare Part D plans. Vellturo Decl. at ¶ 25. Plaintiff suggests that Lupin's generic would likely be given Tier I status, which would mean that a patient's co-payment for Fortamet® would be higher than for the generic drug, likely causing Shionogi to reduce the price of Fortamet®. Pl. Br. Prelim. Inj. 26. This would also contribute to the price erosion created as a result of Plaintiff's lost sales. Vellturo Decl. at ¶¶ 49-53. Lupin responds that Fortamet® "already is a Tier III drug for most formularies," and that "damage stemming from the loss of a formulary position is compensable by monetary damages." Def. Br. Opp. 27.

Finally, Plaintiff argues that "Lupin's launch has now opened the door for Shionogi's licensor, Watson, to introduce its own generic product."[5] Melloy Decl. at ¶ 24. Plaintiff alleges that, although Shionogi receives royalties of 70 percent of Watson's operating profits, "[t]hat royalty will only mitigate the monetary damage to Shionogi," and "will not eliminate the irreparable harm suffered by Shionogi as a result of Lupin's actions." Id. Plaintiff contends that this may also contribute to price erosion. Pl. Br. Prelim. Inj. 27.

3. Compensability of Plaintiff's Losses

Given the projected loss in sales of Fortamet® and the price erosion that is likely to follow, Plaintiff argues that the "steep decline in revenue" that would result if Lupin's launch is not enjoined is not compensable by money damages, because "Shionogi will be forced to cut costs," including a reduction in its work force, and a reduction in its market research efforts. Pl. Br. Prelim. Inj. 25. This would "result in a reduced chance of success" for the U.S. launch of other products, adversely affecting patients and also threatening to "cause Shionogi Japan to reassess the viability of its U.S. operation." Id. (citing Melloy Decl. at ¶ 31 ("If Shionogi Japan

[5] Shionogi indicates that, pursuant to its agreement with Andrx (Watson), it cannot release an "authorized generic" itself. Pl. Br. Prelim. Inj. 26.

were to decide that a U.S. operation is not viable, then Shionogi [U.S.] would likely be shut down and its assets sold off.")).

Lupin, on the other hand, rejoins that "[a]ny harm to Shionogi is clearly quantifiable," and argues that this is proven by Plaintiff's projections of the amount of loss it would suffer as a result of Lupin's launch. Def. Br. Opp. 23. Indeed, Lupin points out that the negative impact "generic competition" has on the brand drug's sales does not "alone . . . establish that [the brand drug's] harm will be irreparable." Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1348 (Fed. Cir. 2006) (indicating that, if the court accepted the notion that a patentee's lost sales demonstrate irreparable harm, such harm would be found "to every manufacturer/patentee, regardless of circumstances").

However, as Shionogi argues, the Federal Circuit has often found price erosion and loss of market share to constitute irreparable harm. See, e.g., Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (determining that "[p]recedent supports [the] conclusion" that "market share and revenue loss" due to the entry of a generic product may constitute irreparable harm, even where other generic products have already inflicted these negative results on the plaintiff); Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (finding "no deficiency" in a district court's finding of irreparable harm on a showing of "likelihood of price erosion and loss of market position"). Moreover, although Defendant contends that even Shionogi's "exaggerated" potential loss "leaves profits of $250 million, more than enough to sustain operations," Def. Br. Opp. 25, it must be noted that the Bosch Court found that "[i]njuries that affect a 'non-core' aspect of a patentee's business are equally capable of being irreparable as ones that affect more significant operations." Bosch, 2011 U.S. App.

LEXIS 20700 at *23. Therefore, Plaintiff's continued livelihood in the face of Defendant's launch is not evidence of a lack of irreparable harm to Shionogi.

Defendant also argues, without contradiction by Plaintiff, that "the Fortamet® market is in steady and irreversible decline, and has been for some time." Def. Br. Opp. 32. Specifically, Lupin points out that Shionogi has projected that the Fortamet® market "will shrink by approximately 25% from 2011 to 2012." Id. This explains why Lupin decided to undertake its at-risk launch when it did; however, it also underscores Plaintiff's argument as to the irreparability of its harm, should Lupin's launch go unenjoined. Given that a "loss of market position without corresponding market expansion" bolsters a plaintiff's case for irreparable harm this Court finds that a loss of market position accompanied by market diminution presents an even stronger case for irreparability. Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (emphasis added).

Therefore, given Shionogi's showing of projected lost sales, price erosion, and lost market share, in concert with its claimed loss of goodwill, Shionogi has adequately demonstrated that it would suffer irreparable harm as defined by the Federal Circuit if Lupin's launch is not enjoined.

**C. Balance of Hardships**

Plaintiff argues that the balance of hardships tips in its favor because, but for Defendant's launch, Plaintiff's product "would continue to account for a substantial percentage of Shionogi's profits going forward." Pl. Reply Br. 19. Lupin argues that it "will suffer serious, and in some instances irreparable, harm" if a preliminary injunction is ordered. Def. Br. Opp. 33. It focuses that claim on the fact that it will lose the 180-day exclusivity period it was granted as "the only non-authorized generic on the market," and will not be able to regain that opportunity, even if it

is successful at trial. Id. However, while this loss of its exclusivity certainly harms Lupin, the Court finds that, on balance, Plaintiff bears the greater hardship in the event that a preliminary injunction is not issued. This is because, as Shionogi notes, the harm suffered by Lupin in the event of an injunction is foreseeable to it. Foreseeability of harm to a party is a factor weighing against tilting the balance of hardships in that party's favor. See, e.g., Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006).

Considering the question of a recall, on the other hand, the Court finds that the balance of hardship weighs in Defendant's favor. As Lupin argues, it would be "onerous, complicated and expensive" for it to recall the product already launched. Def. Br. Opp. 36. Defendant further argues that the costs of a recall would include a loss of goodwill and harm to its reputation with distributors and retailers. Id. at 36-37. Plaintiff does not offer any evidence to suggest that the generic product already released has caused or will cause significant harm to Shionogi; it focuses its argument only on the projected losses should Defendant's launch go unenjoined.

As Defendant explains, a "mandatory injunction is said to alter the status quo by commanding some positive act . . . ." Advanced Oral Techs., L.L.C. v. Nutrex Research, Inc., 2011 U.S. Dist. LEXIS 475 at *6-7 (D.N.J. Jan. 3, 2011) (citing Tom Doherty Assocs. v. Saban Entm't, Inc., 60 F.3d 27, 34 (2d Cir. 1995). Such alteration of the status quo would clearly result from a recall. It therefore "should issue only upon a clear showing that the moving party is entitled to the relief requested, or where extreme or very serious damage will result from a denial of preliminary relief." Id.

It must be noted that Plaintiff agreed to a standstill order that effectively deferred the questions of injunction and recall for one month, and agreed to further extend that standstill agreement for three more weeks, until this Court's hearing concerning its preliminary injunction

motion. That standstill order prevented Lupin from making "new sales or offers to sell" its generic product, or "ship[ping], transfer[ring], or transmit[ting]" its product to third parties, or licensing sales to any third parties. D.I. 216; 273. However, it did not address the issue of recall and allowed the first installments of product released in Lupin's at-risk launch to remain in the channels of commerce. It is difficult to discern why Shionogi's entitlement to a recall has now risen to the level of requiring such an alteration of the status quo, or why "extreme or very serious damage" will now result without a recall, when the recall has not been necessary for nearly two months. Therefore, the Court finds that preliminary injunctive relief will be effective even absent such a mandatory injunction order, and denies Plaintiff's request to recall Lupin's product.

**D. Public Policy**

The public policies competing in this litigation are the interest in increasing the availability of generic drugs, and the enforcement of patent rights and attendant encouragement of innovation. As the Federal Circuit has pointed out, Title I of the Hatch-Waxman Act "was intended 'to make available more low cost generic drugs.'" Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citing H.R. Rep. No. 98-857, pt. 1 at 14 (1984)). Still, the Federal Circuit has also expressed that "[t]he statutory period of [a patentee's] exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest." Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008). Because the relevant patent laws address the public policies at play in both Plaintiff's and Defendant's claims, the Court finds that analysis of this factor is neutral.

## IV. AMOUNT OF BOND

Lupin has requested that the Court order Shionogi to post security, pursuant to Federal Rule of Civil Procedure 65(c),[6] in the amount of $54,000,000. Def. Br. Opp. 37. Lupin claims that this figure "represents the profits Lupin would likely lose over the next two years if it is enjoined, compared to a scenario where it and Watson are competing with Shionogi." Id. Plaintiff argues for bond to be set in a range of $10,000,000 to $15,000,000. Dec. 2, 2011 Hearing.

The amount of the security bond under Fed. R. Civ. P. 65(c) is controlled by Third Circuit law. International Game Tech. v. WMS Gaming Inc., 1999 U.S. App. LEXIS 22971 at *3 n.1. (Fed. Cir. Sept. 3, 1999) ("Because the amount of the security bond is a procedural issue not unique to patent law, we apply the law of the regional circuit where the appeal from the district court would normally lie . . . ."). The Third Circuit has held that a district court should set "such bond as it determines to be appropriate to secure payment to [the enjoined party] of any compensable money damages that it may incur prior to final disposition of this matter should it be determined that [the enjoined party] was erroneously enjoined. In determining the amount of such bond, the district court should, of course, take into account [the enjoined party's] ability to minimize the potential for such damages." Kos Pharms., Inc. v. Andrx Corp., 369 F.3d 700, 732 (3d Cir. 2004).

The parties estimate, and the Court agrees, that judgment in this case will be reached in about one year. Accordingly, the security bond should approximate the potential loss to Lupin over the next year, assuming a judgment ultimately in Lupin's favor. The Court finds that the most likely circumstances that would confront Defendant, were its launch not enjoined, is the

[6] "The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c).

scenario referred to by its expert as "Scenario C." Hoffman Decl. at ¶ 19. Scenario C reflects a situation wherein Lupin launched as planned, Watson would launch soon after, and Mylan would launch in July 2012. Id. Defendant's expert estimates that this scenario would yield $28,348,700 in net sales in the first year. Id. However, as Defendant has often pointed out, its greatest profits would be accrued during the 180-day exclusivity period afforded to it by the Hatch-Waxman statute. Def. Br. Opp. 33. Furthermore, over a month of that exclusivity has already been lost to the parties' extended standstill agreements. The Court orders Plaintiff to post a security bond of $15,000,000.

## V. CONCLUSION

Balancing the four factors of the preliminary injunction test, the Court finds that the analysis weighs in favor of granting Shionogi's request for a preliminary injunction. However, the Court declines to order a recall of Lupin's already-released generic product. Finally, the Court orders Plaintiff to post $15,000,000 in security, pursuant to Federal Rule of Civil Procedure 65(c).

Dated: 12/6/2011

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge